

# CORECEPTOR TROPISM ASSAYS



## Trofile® and Trofile® DNA provide critical information for informed treatment decisions

HIV-1 can attach to human cells either by using the CCR5 coreceptor, the CXCR4 coreceptor, or both (dual/mixed). Tropism testing determines how the virus can attach to the cells in a given patient. Possible tropism results are R5, DM, X4, and X4 near the limit of detection (NLOD).

### Why does my patient's tropism matter?

HIV tropism results can help you develop a personalized treatment plan for your patient. Appropriate use of CCR5 antagonists including maraviroc requires that an HIV tropism test be performed before initiation of therapy.<sup>1</sup>

### Trofile®

A highly sensitive assay that provides critical information when selecting a treatment regimen containing maraviroc

- Trofile was utilized to identify treatment candidates in the maraviroc multicenter clinical trials.<sup>1</sup>
- Both the current DHHS and IDSA guidelines recommend tropism testing before initiation of treatment with a CCR5 antagonist.<sup>2,3</sup>
- Trofile is the only commercially available tropism assay that has been clinically validated through use in Phase 2 and Phase 3 clinical studies to identify CCR5 antagonist candidates.<sup>4,6</sup>

### Trofile® DNA

Applies the proven performance of Trofile to cell-associated viral DNA

Consider Trofile® DNA when a patient's viral load is undetectable, tropism is unknown, and substitution with a CCR5 antagonist-containing regimen is desired. Regimen substitution may be considered when<sup>2</sup>

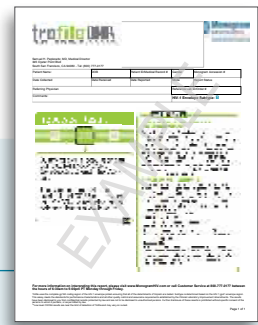
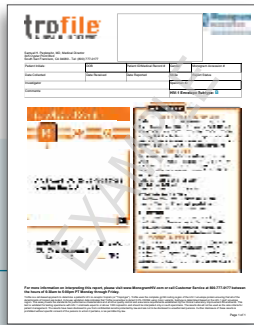
- Laboratory results or clinical adverse events necessitate a change<sup>7,8</sup>
- Patient exhibits intolerance to the current regimen<sup>7</sup>
- There is concern regarding the long-term effects of the current regimen<sup>8</sup>

### GenoSure Archive® Plus Trofile® DNA

Comprehensive suppression management profile

Designed to provide a comprehensive assessment of five antiretroviral drug classes (GenoSure Archive: NRTIs, NNRTIs, PIs, INIs and Trofile DNA: CCR5 antagonist) to facilitate regimen simplification or switches in the setting of virologic suppression.

Monogram Biosciences and LabCorp are pleased to offer options in HIV-1 coreceptor tropism testing.



## trofile<sup>®</sup>

CO-RECEPTOR TROPISM ASSAY

LabCorp test: 553100

Consider Trofile<sup>®</sup> when<sup>1</sup>

- Patients have a viral load of  $\geq 1000$  copies/mL

### Assay features include

- Phenotypic analysis of viral RNA
- Analytically and clinically validated to screen patients prior to initiation of maraviroc\*

### Specimen Requirements\*\*

3mL plasma, EDTA or PPT tube, frozen

## trofile<sup>®</sup> DNA

CO-RECEPTOR TROPISM ASSAY

LabCorp test: 829670

Consider Trofile<sup>®</sup> DNA when<sup>9,10</sup>

- Patients have an undetectable viral load

### Assay features include

- Phenotypic analysis of cell-associated viral DNA
- Assay performance characteristics analytically validated

### Specimen Requirements\*\*

4mL whole blood, EDTA tube, frozen

For additional test information, including specimen requirements, CPT coding and RUO/IUO status, consult the Online Test Menu at [www.LabCorp.com](http://www.LabCorp.com).

Coverage support and assistance for Trofile<sup>®</sup>, Trofile<sup>®</sup> DNA, and Trofile<sup>®</sup> Select are available through Gateway at 877-436-6243.

\* Trofile<sup>®</sup> was clinically validated in the maraviroc registrational studies.

\*\* When ordered separately/individually

## Trofile<sup>®</sup> Select

Consider Trofile Select when tropism testing is desired and viral load is unknown.

Allows for ordering of Human Immunodeficiency Virus 1 (HIV-1) coreceptor tropism status to be completed using the appropriate assay, Trofile<sup>®</sup> or Trofile<sup>®</sup> DNA, based on the results of an initial prescreening viral assessment by the laboratory. The coreceptor tropism status may be used to determine eligibility for CCR5 antagonist therapy such as maraviroc (Selzentry<sup>®</sup>).

Test Name	Test Number	Specimen Requirements
Trofile <sup>®</sup> Select	553355	5mL plasma, EDTA tube, frozen and 4mL whole blood, EDTA tube, frozen
GenoSure Archive <sup>®</sup> Plus Trofile <sup>®</sup> DNA	552020	8mL whole blood, EDTA tube, frozen

### References

1. SELZENTRY<sup>®</sup> (maraviroc) prescribing information. Pfizer Labs division of Pfizer Inc., New York, NY. November 2009.
2. US Department of Health and Human Services. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Available at: <http://www.aidsinfo.nih.gov/Guidelines/Default.aspx?Menuitem=Guidelines&Search=On>. Accessed May 2014.
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4. Hardy WD, Gulick R, Mayer H, et al. Efficacy and safety of maraviroc in treatment-experienced (TE) patients infected with R5 HIV-1: 96-week combined analysis of the MOTIVATE 1 and 2 studies. Poster presented at: Ninth International Congress on Drug Therapy in HIV Infection; November 9-13, 2008; Glasgow, UK. Poster O425.
5. Saag M, Heera J, Goodrich J, et al. Reanalysis of the MERIT study with the enhanced Trofile<sup>®</sup> assay (MERIT-ES). Program and abstracts of the 48th Annual ICAAC/IDSA 46th Annual Meeting; October 25-28, 2008; Washington, DC. Abstract H-1232a.
6. Cooper DA, Heera J, Goodrich J et al. Maraviroc versus efavirenz, both in combination with zidovudine-lamivudine, for the treatment of antiretroviral-naïve subjects with CCR5-tropic HIV-1 infection. *J Infect Dis*. 2010;201:803-813. 7
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8. Eron JJ, Cooper DA, Youle M, et al. Switch to a raltegravir-based regimen versus continuation of a lopinavir-ritonavir-based regimen in stable HIV-infected patients with suppressed viraemia (SWITCHMRK 1 and 2): two multicentre, double-blind, randomised controlled trials. *Lancet*. 2010 Jan 30;375(9712):396-407.
9. Toma J, Frantzell A, Cook J, et al. Phenotypic determination of HIV-1 coreceptor tropism using cell-associated DNA derived from blood samples. Paper presented at: Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC); September 12-15, 2010; Boston, Mass.
10. Tashima KT, Coakley E, Toma J, et al. A comparison of DNA and plasma Trofile results in a treatment experienced study population prior to initiation of new antiretroviral regimens. Abstract presented at: the International Workshop on HIV & Hepatitis Virus Drug Resistance and Curative Strategies; June 7-11, 2011; Los Cabos, Mexico. Abstract 91.

